



Docket No.: 64693-101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of : Customer Number: 33401  
SHEHADA, Ramez E.N. et al. : Confirmation Number: 1453  
Serial No.: 10/776,022 : Group Art Unit: 3762  
Filed: February 9, 2004 : Examiner: Not Known  
For: SURGICAL DRAIN WITH SENSORS FOR DIFFERENTIAL MONITORING  
OF INTERNAL CONDITION

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450 on December 28, 2004.

Signed: \_\_\_\_\_

Jessica S. Brown

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.56**

Sir:

Pursuant to 37 C.F.R. § 1.56, § 1.97 and § 1.98, Applicant brings the references listed on the attached Form PTO-1449 to the examiner's attention. 37 C.F.R. § 1.56. These references may be material to examination of the above-identified application. Please do not construe the filing of this information disclosure statement as a representation that applicant has made a search (37 C.F.R. § 1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. We enclose copies of those cited documents that are not patents or published patent applications.

This Information Disclosure Statement is being submitted:

- ☒ 1. Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first Office action on the merits, and therefore, Applicant believes no fee is required;

- ☐ 2. After the period specified in paragraph (1) hereinabove of this section, but is being filed before the mailing date of either a final action under 37 CFR 1.113, or a notice of allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by one of the following:
- ☐ (a) A statement that either:
- (i) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;
- OR
- (ii) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement;
- OR
- ☐ (b) The fee of \$180 for filing of an Information Disclosure Statement as set forth in 37 C.F.R. 1.17(p).
- ☐ 3. After the period specified in paragraph (2) of this section, but is filed on or before payment of the issue fee and is accompanied by both:
- ☐ (a) A statement that either:
- (i) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;
- OR
- (ii) No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement;
- ☐ (b) The fee of \$180.00 for filing of an Information Disclosure Statement as set forth in 37 CFR 1.17(p).

Applicant would appreciate the Examiner initialing and signing a copy of Form PTO-1449, transmitted herewith, indicating that the information has been considered and made of record herein.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the

cost of such petitions and/or other fees due in connection with the filing of this document to

**Deposit Account No. 501946** referencing order number 64693-101-6806

December 28, 2004

  
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/776,022
				Filing Date	February 9, 2004
				First Named Inventor	SHEHADA, Ramez E.N.
				Art Unit	3762
				Examiner Name	Not known
Sheet	1	Of	4	Attorney Docket Number 64693-101	

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number -Kind Code <sup>2</sup> (if known)	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	US-6,556,851	04-29-2003	Ott et al.
	2	US-6,547,761	04-15-2003	Liu
	3	US-6,491,682	12-10-2002	Paderni
	4	US-6,437,855	08-20-2002	Wilson et al. (Honeywell International Inc., Assignee)
	5	US-6,411,838	06-25-2002	Nordstrom et al.
	6	US-6,334,064	12-25-2001	Fiddian-Green
	7	US-6,134,460	10-17-2000	Chance
	8	US-5,965,873	10-12-1999	Simpson et al. (Lockheed Martin Energy Research Corporation, Assignee)
	9	US-5,916,171	06-29-1999	Mayevsky
	10	US-5,746,207	05-05-1998	McLaughlin et al.
	11	US-5,685,313	11-11-1997	Mayevsky (Brain Monitor Ltd., Assignee)
	12	US-5,645,062	07-08-1997	Anderson et al.
	13	US-5,512,045	04-30-1996	Gurchumelidze
	14	US-5,349,961	09-27-1994	Stoddart et al.
	15	US-5,337,748	08-16-1994	McAdams et al.
	16	US-5,108,364	04-28-1992	Takezawa et al.
	17	US-5,106,387	04-21-1992	Kittrell et al.
	18	US-4,721,115	01-26-1988	Owens
	19	US-4,654,029	03-31-1987	D'Antonio
	20	US-4,416,285	11-22-1983	Shaw et al.
	21	US-4,317,452	03-02-1982	Russo et al.
	22	US-3,866,599	02-18-1975	Johnson

**U.S. PUBLISHED PATENT APPLICATIONS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number -Kind Code <sup>2</sup> (if known)	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	23	US2002/0082587 A1	06-27-2002	Noda

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

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<b>OTHER PRIOR ART – NONPATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
	24	BUISE, M.P. et al. Reflectance Spectrophotometry and Tissue Oxygenation in Experimental and Clinical Practice. Abstract only. (A printed publication published prior to February 9, 2004.)			
	25	CORDIS (Community Research & Development Information Service). Description of MICROTRANS (Microprobe multi-sensor for graft viability monitoring during organ preservation and transplantation) Project. 5 pages. (A printed publication published prior to February 9, 2004.)			
	26	FERTMANN, J.M. et al. Measurement of Regional Perfusion and Oxygen Saturation During Human Simultaneous Pancreas-Kidney Transplantation – Correlation with Intravital Microscopy. (A printed publication published prior to February 9, 2004.) Poster.			
	27	HÖLZLE, F. et al. Donor Site Morbidity of the Osteocutaneous Fibula Flap. Abstract only. In Abstracts of the 16th Congress of the European Association for Cranio-Maxillofacial Surgery, 3-7 September 2002, Münster, Germany.			
	28	HÖLZLE, F. et al. Nutritive Perfusion at Donor Site After Microvascular Fibula Transfer. Abstract only. In Microsurgery. 2003; 23(4): pp. 306-312.			
	29	HÖLZLE, F. et al. The Radial Artery as a Carrier of the Osteocutaneous fibula Flap for Reconstruction of the Mandibula. Abstract only. In Abstracts of the 16th Congress of the European Association for Cranio-Maxillofacial Surgery, 3-7 September 2002, Münster, Germany.			
	30	KAKIHANA, Y. et al. Effects of Ligustrazine on Hepatic Oxygenation in Isolated Perfused Rat Liver. Abstract only. In Vivo, Jan-Feb 1999; 13(1):pp. 29-34.			
	31	KASLER, M. et al. [Noninvasive Intraoperative Measurement of Intracapillary Hemoglobin Oxygenation and Relative Hemoglobin Concentration in Surgical Skin Flaps.] (article in German). Abstract only. In HNO, Oct. 1990; 38(10): pp. 375-378.			
	32	KRUG, A. Non-Invasive Oxygen and Perfusion Monitoring. Abstract only. In Danish Microsurgical Society, Hindsgavl Congress, 21-22 March 2002.			
	33	LEA MEDIZINTECHNIK. Tissue Blood Supply after Transplantation of a Pedicled Flap-Microcirculation Two Days and One Week After Surgery and Flap Conditioning. Abstract only. (A printed publication published prior to February 9, 2004.)			
	34	LEA MEDIZINTECHNIK. Tissue Neovascularisation One Week After Transplantation. Abstract only. (A printed publication published prior to February 9, 2004.)			
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	35	LEA MEDIZINTECHNIK. Viability of Flaps: Intra- and Postoperative Monitoring for Increase of Transplantation Success Rate. (A printed publication published prior to February 9, 2004.)			
	36	LEA MEDIZINTECHNIK. Postoperative Long-Term Monitoring. Abstract only. (A printed publication published prior to February 9, 2004.) 3 pages.			
	37	LEA MEDIZINTECHNIK. Company Profile LEA Medizintechnik GmbH. (A printed publication published prior to February 9, 2004.)			
	38	LEA MEDIZINTECHNIK. O2C Oxygen To See. Price List. (A printed publication published prior to February 9, 2004.) 3 pages.			
	39	LEA MEDIZINTECHNIK. Fields of Application of O2C Oxygen To See. (A printed publication published prior to February 9, 2004.) 3 pages.			
	40	LEA MEDIZINTECHNIK. What Measures O2C Oxygen To See? (A printed publication published prior to February 9, 2004.) 1 page.			
	41	LEA MEDIZINTECHNIK. O2C Oxygen To See: Measurements of Tissue Circulation, Saturation of Hemoglobin SO <sub>2</sub> , Local Amount of Hemoglobin. (A printed publication published prior to February 9, 2004.) 6 pages.			
	42	LEA MEDIZINTECHNIK. O2C (Oxygen To See): Perfusion of Tissue; Capillary-Venous Oxygen Saturation; Blood Filling of Microvessels. (A printed publication published prior to February 9, 2004.) 3 pages.			
	43	LEA MEDIZINTECHNIK. O2C Probes. (A printed publication published prior to February 9, 2004.)			
	44	LEA MEDIZINTECHNIK. Micro Probes. (A printed publication published prior to February 9, 2004.)			
	45	LOEFFELBEIN, D. et al. Combined Non-Invasive Tissue Oxygen and Flow Monitoring in Fasciocutaneous Forearm Flaps. Abstract only. (A printed publication published prior to February 9, 2004.)			
	46	MAYEVSKY, A. et al. Real-time optical monitoring of tissue vitality in vivo. In Optical Fibers and Sensors for Medical Applications. II. I. Edt Gannot. Proceedings of SPIE, 2002; 4616:pp. 30-39.			
	47	MICROTRANS. Micro Probe Multisensor for Graft Viability Monitoring During Organ preservation and Transplantation. Company and Product Information. (A printed publication published prior to February 9, 2004.) 13 pages.			
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	48	NOLTE, D. et al. Simultaneous Non-Invasive Fluxmetry and Tissue Oxygen Monitoring in Fasciocutaneous Flaps. Abstract only. In Abstracts of the 16th Congress of the European Association for Cranio-Maxillofacial Surgery, 3-7 September 2002, Münster, Germany.			
	49	OAK RIDGE NATIONAL LABORATORY. Science and Technology. Institution and Research Information. (A printed publication published prior to February 9, 2004.)			
	50	SIMONSEN, M. Remote Diagnostics and Patient Monitoring Developments. (BBI at the MEDICA 2002 Exhibition). Abstract only. In BBI Newsletter, January 2003.			
	51	SOMMER, N. et al. Case Study: Microcirculatory Measurements in Chronic-venous Insufficiency (CVI) and Lipedema With O2C (Oxygen to See) – Observation of Effectivity of Physical Therapy. (A printed publication published prior to February 9, 2004.) Poster.			
	52	STIRBAN, ALIN et al. Differential Role of Type 2 Diabetes and Cardiovascular Autonomic Neuropathy in Impaired Control of Skin Microcirculation. Poster. (A printed publication published prior to February 9, 2004.)			
	53	UNIVERSITY OF ULSTER. Microtrans. From News and Events Archive 2000. 2 pages			
	54	UNIVERSITY OF ULSTER. UU Unveils Lifesaving Organ Transplant Sensor Technology. May 22, 2002. 2 pages.			
	55	VITAL MEDICAL LTD. Multiparametric Monitoring of Tissue and Body Vitality in Real time. Company and Product Information. (A printed publication published prior to February 9, 2004.) 13 pages.			
	56	WOLFF, K.D. et al. Hemoglobin Oxygenation of Venous-Perfused Forearm Flaps. Abstract only. In 1: Ann. Plast. Surg., Dec. 1998; 41(6): pp. 646-652; discussion pp. 652-653.			
	57	WOLFF, K.D. et al. Monitoring of Flaps by Measurement of Intracapillary Haemoglobin oxygenation with EMPHO II: Experimental and Clinical Study. Abstract only. In Br. J. Oral Maxillofac. Surg., Dec. 1996; 34(6):pp. 524-529.			
	58	WOLFF, K.D. et al. Cutaneous Hemoglobin Oxygenation of Different Free Flap Donor Sites. Abstract only. In Plast. Reconstr. Surg., Oct. 1998; 102(5):pp. 1537-1543.			
	59	WOLFF, K.D. et al. Intracapillary Haemoglobin Oxygenation and Interstitial pO2 in Venous Flaps: An Experimental Study in Rats. Abstract only. In Microsurgery 1998; 18(5):pp. 324-330.			
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